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Dusan Miljkovic

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FISH & ASSOCIATES, PC

ROBERT D. FISH

2603 Main Street

Suite 1000

Irvine, CA 92614-6232

EXAMINER

MEHTA, HONG T

ART UNIT

PAPER NUMBER

1794

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,945	Applicant(s) MILJKOVIC ET AL.	
	Examiner HONG MEHTA	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 11, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>April 16, 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on March 11, 2009. Pending amended claims 1-20 are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the board recitation of the food product preparation of a whole coffee cherry, but then claim

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4 recites "...coffee cherry further comprises at least one of bean of the coffee cherry, a pulp of the coffee cherry, a mucilage of the coffee cherry and a hull of the coffee cherry" and the claim 4 depend upon claim 1 also recites "...whole coffee cherry wherein the coffee cherry..." which is the narrow statement of the range/limitation. It is not clear if the preparation of claim 1 is from the "whole coffee cherry" which would include all parts of the cherry, or if it part of the cherry as indicated in claim 4. Claim 4 recites the limitation of the coffee cherry, as being contradictory to claim 1. Please clarify.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 4, 6-11, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sivetz et al. (Coffee Technology 1979).**

6. **Regarding claim 1, 4, 19 and 20**, Sivetz et al. discloses a preparation of whole coffee cherry (pg. 76, line 12), harvested in all stages of ripeness (pg. 76, line 7), including green coffee cherry (pg. 76, line 11) and quick-dried as a whole fruit with mechanical driers or on the sun-drying terrace to make a *natural* coffee, a food product (pg. 76, line 13-14). Sivetz et al. discloses the strip-picked heterogeneous mixture, including green coffee cherry, ripe and soft overripe which vary in proportions as harvest season progress, are made into *natural* coffee (pg. 86, paragraph 86). Sivetz et al. discloses process of drying process (pg. 82, paragraph 3) of the coffee cherry into

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natural coffee wherein producing an excellent quality, clean tasting and full bodied coffee foodstuff upon human consumption.

7. Examiner considers Sivetz's preparation of whole coffee cherry to exposure to sun-drying terrace and mechanical driers as quick-dried preparation, as defined in Applicant's specification as using heated air exposure to sun and/or ambient air on page 3, lines 24-26.

8. Sivetz et al. discloses the cherries to be sub-ripe coffee cherry in all stages of ripeness, including green color (pg. 76, lines 11) are harvest and to be processed by quick-drying. Sivetz et al. discusses the high moisture content in coffee promotes the growth of microorganism such as molds, fungi and bacteria (pg. 81, para. 2, pg. 127, para. 3; pg. 128). As Applicant disclose "...mycotoxins are typically present in substantial quantities in ripe and overripe coffee cherries, whereas quick-dried sub-ripe coffee cherries or portions thereof, are substantially devoid or have very low content of mycotoxins" (page 3, paragraphs 2 and 3). Sivetz et al. is silent on the quick-dried cherry having a designated myotoxin levels. Examiner considers Sivetz's harvest preparation in all stage of ripeness of coffee cherries (pg. 76, lines 15-16) to include sub-ripe coffee cherries, which includes cherry coffee which has not yet reached the ripe stage.

9. As Sivetz et al. uses like material in a like manner as claimed, it would therefore be expected that the quick-dried coffee cherry will have the same characteristics claimed, particularly the myotoxin level, absent a showing otherwise.

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10. It is further expected that the composition of Sivetz et al. would fall within the scope of claim 1 and 19, since the claimed end product may encompass a wide range of amount of mycotoxin, aflatoxin, fumonisins and ochratoxins depending on the way in which the product is produced, the source within the coffee cherry and the ratio of the coffee cherry to other ingredients are employed. Due to the natural present of a preservative in coffee cherry, it is further expected that the amount of the same in the product of the Sivetz et al. would provide the same amount of preservative effect. Furthermore, the claims include mycotoxin levels of zero, cited "less than", and no mention of these mycotoxins is mentioned in Sivetz et al.

11. **Regarding claims 6, 7 and 8**, Sivetz et al. discloses the ripe coffee fruit, losing chlorophyll, green to yellow to red as the cherry coffee fruit matures for coffee processing (pg. 74, paragraph 3) and is stripped off in all stages of ripeness (pg. 76, paragraph 2). Sivetz et al. discloses green coffee cherries without red color and blemished area (pg. 76, paragraph 3) to be dried either mechanical drier for "quick drying" or on the sun-drying, solar radiation in ambient air terrace for coffee processing. Sivetz et al. discloses the mixture of cherry coffee may be as high as 15% of green cherry coffee fruit to red cherry coffee fruit at beginning stage of coffee processing harvest (pg. 75).

12. **Regarding claim 9, 10, and 11**, Sivetz et al. discloses a preparation of whole coffee cherry (pg. 76, line 12), harvested in all stages of ripeness (pg. 76, line 7), including green coffee cherry (pg. 76, line 11) and quick-dried as a whole fruit with

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mechanical driers or on the sun-drying terrace to make a natural coffee, a food product (pg. 76, line 13-14).

13. "[E]ven though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (*In re Thorpe*, 227 USPQ 964,966).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivetz et al. (Coffee Technology 1979) and Drunen et al. (US 6,572,915 B1), and in further view of Johnson et al. (US 2,526,872), Soucy (US 6,202,321), Bucheli et al., Batista et al., Frank, Helferich, Romani et al., Codex Committee on Food Additives and Contaminants (CCFAC) and the United States Food and Drug Administration or USDA. (Newly applied as necessitated by amendment.)

18. If the levels of toxins in the coffee cherries of Sivetz are not considered to be inherent based upon the ripening stage, the following rejection is made. Sivetz et al. discloses a preparation of whole coffee cherry (pg. 76, line 12), harvested in all stages of ripeness (pg. 76, line 7), including green coffee cherry (pg. 76, line 11) and quick-dried as a whole fruit with mechanical driers or on the sun-drying terrace to make a natural coffee, a food product (pg. 76, line 13-14).

19. Sivetz et al. discusses the high moisture content in coffee promotes the growth of microorganism such as molds, fungi and bacteria (pg. 81, para. 2). However, Sivetz et al. does not specifically teach the levels of a mycotoxin level of the cherry is less than 20 ppb for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fomonisins.

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20. However, it would have been obvious to one of ordinary skill in the art to use the quick-dried whole coffee cherry used in making natural coffee foodstuff by Sivetz et al. with the claim-designated ingredient to provide the instantly claimed invention because at the time the invention was made the following was well known in the art of botany, mycology and the coffee industry.

21. **Firstly**, prior studies showed that *Aspergillus*, *Penicillium* and *Fusarium* are natural coffee contaminants having the potential to produce aflatoxins, ochratoxins, and fumonisins which are detrimental to the quality and safety of the final product. Attention is invited to Batista et al., for instance, wherein Batista clearly teaches, "Like the other crops, coffee cherries and beans are subjected to contamination and consequent colonization by microorganisms during different phases of development, harvesting, transport and storage. Microbial action detrimental to the quality and safety of the final product will depend on environmental conditions as well as crops and product management. Studies on the microbiology of coffee cherries and beans have shown the main toxigenic fungal genera (*Aspergillus*, *Penicillium* and *Fusarium*) are natural coffee contaminants and are present from the field to the warehouse" (pg. 293-294).

22. While the teaching of Frank also teaches, "Lastly, a fresh cherry sample can be manipulated in the laboratory to assess the consequences of the hypothetical circumstances such as a heavy superficial contamination of a particular fungus or removal of the natural external microbial flora" (pg. 6, para. 3). Frank teaches that a harvest aspergilli, such as *A. ochraceus* (and other species with similar physiological

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properties) and OTA production is restricted to a fairly narrow window between A_w values of 0.94 and 0.80. Like Frank, Helferich teaches that aflatoxins are contaminants of agricultural crops, such as coffee. Helferich teaches, "Aflatoxins have become generally accepted to be poisonous and deleterious, and are now widely regulated in foods. In the U.S., the Food and Drug Administration (FDA) regulates feed and food containing aflatoxins at regulatory levels of 20 ppb of AFB for human foods and selected animal feed" (pg. 108, para. 2). Helferich further teaches that ochratoxins are toxins found in coffee; and, that heat treatment at 250°C for 40 minutes provides a 76% reduction of the toxin in white flour (pg. 108-109, under "Ochratoxin A").

23. Furthermore, Romani teaches that international statutory limits for ochratoxin A (OTA) as regulated by Italy are 8 ppb for green coffee and 4 ppb for final product; 10 ppb as regulated by Finland, and 20 ppb as regulated by Greece. While the teaching of Codex Committee on Food Additives and Contaminants (CCFAC), with regard to fumonisins are predominantly directed to its occurrence in cereal grains, CCFAC teaches that *Fusarium* growth and mycotoxin production may continue to grow in agricultural crops if they are not sufficiently dried and that is when the content of small grain is reduced to approximately 15% growth of *Fusarium* species will stop.

Furthermore, the FDA teaches, "The recommended maximum levels fumonisins in corn and corn products intended for human consumption (Table 1) are based on concerns associated with hazards shown primarily by animal studies. However, based on available information on the occurrence of fumonisins, FDA believes that typical fumonisin levels found in corn and corn products intended for human consumption are

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much lower than recommended level. For example, Table 1 indicates levels of 2-4 ppb of fumonisins in corn are acceptable levels for human consumption.

24. **Secondly**, each of Johnson, Mann and Soucy teaches quick-dry methods for reducing the number of toxigenic fungal genera and mycotoxin contaminants in whole coffee cherry or an agricultural crop of economic importance wherein the mycotoxins may occur. For instance, Johnson teaches a method of preventing, eliminating or minimizing fermentation and enzymolysis caused by the action of microorganisms, including yeast, bacteria, and molds on whole coffee cherry by rapidly drying the whole cherry (col. 1, lines 1-24; col. 2, lines 53-54).

25. Next, Mann teaches a method for lowering the alfatoxin level in an agricultural product contaminated with alfatoxin by heat treatment for a period time sufficient until the level of alfatoxin, as measured by chemical assay, ranges from about 3 to about 14 ppb.

26. In another example, Soucy teaches a process for drying whole coffee beans, coca beans (whole coffee cherry), and various grains; and a method of use thereof. Soucy further teaches that drying process is performed in an apparatus for the removal of moisture from bulk moisture content. Finally, Bucheli, demonstrates that reduction of ochratoxin in coffee plant materials of coffee cherry can be achieved by properly drying whole fruit of the *Coffea sp.* Under optimal conditions and within a short period of time after harvesting. Bucheli also teaches that the condition of ochratoxins in coffee cherries is directly related to the coffee cherry maturity. For instance, Bucheli, teaches

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that no evidence for the formation of ochratoxin is observed when unripe whole coffee cherry are dried within 1-5 days after harvesting (Table 3 and Table 4).

27. Sivetz et al. is silent on the preparation of food product comprising of “comminuted” crushed coffee cherry, extracts and ground fragments in cited claims. Drunen et al. teaches a food product prepared from coffee cherry (Abs., col. 52-55) and quick dried (col. 3, lines 7-8). Drunen et al. teach a process by which the antioxidants are extracted (col. 2, lines 18-48). It is further expected that the composition by process of Drunen et al. would fall within the scope of claim 1, 15, 16 and 19, since the claimed end product may encompass a wide range of amount of mycotoxin, aflatoxin, fumonisins and ochratoxins depending on the way in which the product is produced, the source within the coffee cherry and the ratio of the coffee cherry to other ingredients are employed. Due to the natural presence of a preservative in coffee cherry, it is further expected that the amount of the same in the product of the Drunen et al. would provide the same amount of preservative effect. Furthermore, the claims include mycotoxin levels of 0, and no mention of these mycotoxins is mentioned in Drunen et al.

28. **With respects to claims 2 and 3**, Drunin et al. teaches food product wherein the coffee cherry comprises a ground fragment of the coffee cherry (col. 4, Example III, line 46; Example IV, line 61; col. 5, Example V, line 8); extract from ground fragment of coffee cherry (col. 3, lines 34-37, 47-54 and 60-62).

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29. **With respects to claims 5**, Drunin et al. teaches food product wherein the coffee cherry comprises extract (col. 3, lines 60-62) of hull (col. 1, lines 18-19); pulp (col. 4, Example I, line 3); bean and mucilage (col. 1, line 59).

30. **With respects to claims 12, 13 and 15**, Drunin et al. teaches food product coffee extract to be incorporated into soluble coffee for a coffee beverage for human consumption. It is universal accepted terminology that the term beverage encompass coffee and tea drinks (col. 1, line 14) whereas the term, tea may be generic term to such an infusion of plant material with hot water produced an aqueous extraction of flavors, aromas and exacts in an infused tea beverage.

31. **With respects to claim 14**, Drunin et al. teaches food product is nutritional supplement in liquid or solid form and comprising an extract of the coffee cherry (col. 3, lines 35-44).

32. **With respects to claim 17**, Drunin et al. teaches block of natural extract foodstuff of coffee cherry with polyphenol concentration (col. 3, lines 47-53) to be use in part of a beverage.

33. It would have been obvious to one of ordinary skill in the art, to employ the preparation of Drunin's extraction of comminuted coffee cherry into Sivetz's preparation of quick-dried whole coffee cherry for natural coffee food product. Drunen's method of extraction of comminuted coffee cherry and blending the coffee cherry extracts enriches the end food product with beneficial agents present in the processes waste products such as coffee cherries (Abstract).

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34. The teachings of Johnson, Soucy and Mann taught that quick-drying of whole coffee cherries or portions thereof or the quick-drying of agricultural crops susceptible to mycotoxin contamination is useful in the drying of the coffee plants materials provide for a more microbial stabilized dried food product by reducing the killing bacteria and molds present on or in coffee plant parts, as well as inactivate or substantially reduce mycotoxins. One would have reasonably expected that the quick-drying process methods for drying or lowering the water activity or reducing the mycotoxin level of coffee product or an agricultural crop as taught by Johnson, Soucy and Mann would be equally applicable to a whole coffee cherry that was not maturely ripe, "sub-ripe" as taught be successful in the quick-drying of coffee beans or other agricultural products by the references because it would have been no more than matter of routine optimization to provide the result effect variable for the reduction of microbial growth or myotoxin by varying the experimental parameters known to be useful in controlling, preventing or minimizing the growth of mycotoxin-producing *Aspergillus*, *Penicillin* and *Fusarium* or inactivation of mycotoxins produced thereby, as taught by Helferich, Frank, and the CCFAC; and the experimental parameters for the drying of the coffee cherries used in the protocol of sample preparation as taught by Bucheli to assess ochratoxin production in cherries suggested that oven-drying at 70°C and/or freeze-drying of coffee cherries within a minimum time after fruit harvesting greatly reduces the production of ochratoxin and that accelerates drying coffee cherries provides for a dried coffee cherry with either low detection or no detection of mycotoxins of varying ranges of ripeness or time of harvest. One of ordinary skill in the art would have recognized to such a modification to

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the teachings of Sivetz et al. and Drunen et al. would be successful because it would address the concern of the international community for the occurrence of mycotoxins in products prepared from coffee cherry intended for human or animal consumption since it is known that aflatoxins, ochratoxins and fumonisins pose risk to the health of humans and animals and would meet the requirements for limited levels of mycotoxins in food crops as regulated by agencies such as FDA. This reasonable expectation of success would motivate the skill artisan to modify the teachings of Sivetz et al. and Drunen et al. to arrive at the instantly claimed composition.

35. Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time of the invention was made, especially in the absence of to the contrary.

Response to Arguments

36. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection. Applicant amended claims 1, 4, 5, 15 and 19 to recite a "whole coffee cherry" which changed the limitation of the claims which necessitated new grounds of rejections to the claimed invention.

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG MEHTA whose telephone number is (571)270-7093. The examiner can normally be reached on Monday thru Thursday, from 7:30 am to 4:30 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/JENNIFER MCNEIL/

Supervisory Patent Examiner, Art Unit 1794